

Application No. 10/740,747
Reply to Office Action dated June 12, 2007
Reply to Office Action of June 05, 2007

traversal of the restriction requirement, and Applicant submits that the withdrawal of claims 1 and 10-18 in the present Office Action is improper. Accordingly, Applicant respectfully requests consideration of claims 1 and 10-18 and 19-31 together.

According to MPEP § 2142, to establish a prima facie case of obviousness under 35 U.S.C. § 103(a), the following three (3) basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Accordingly, if no motivation exists to modify the implant Brantigan '915 with the teachings of Johnson, then the Examiner would have failed to make a prima facie case of obviousness. Moreover, if the implant of Brantigan '915 was modified with the teachings of Johnson, and the apparatus resulting from the modification did not include all the claim limitations, then the Examiner would have also failed to make a prima facie case of obviousness.

Applicant submits that independent claim 19 is patentable over the Examiner's rejection under 35 U.S.C. § 103(a). Moreover, although not considered in the present Office Action, Applicant also submits that independent claim 1 is patentable over the Examiner's rejection under 35 U.S.C. § 103(a). Independent claim 19 recites an implant for insertion in part between two portions of bone comprising a body with an exterior surface, and "at least one surface projection extending from said exterior surface...configured to resist backward rotation of said body once said body has been inserted between the portions of bone." Furthermore, independent claim 1 recites a device for insertion between two boney structures comprising an elongated body with an outer surface, and "a helical thread formed on at least a portion of said outer surface...including at least one deviation adapted to resist backward rotation of said elongated body once it is inserted between the boney structures."

In accordance with independent claims 1 and 19, Applicant's specification, for example, discloses an implant 50 including locking threads 53 provided on the exterior

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thereof. As shown in Fig. 4D, the implant 50 is configured for placement between vertebrae V. Furthermore, the locking threads 53 are adapted to prevent dislodgement of the implant 50 from between the vertebrae V. For example, the locking threads 53 include "a series of interjections, the ends of which are blunted and twisted so as to resist unscrewing." (Corresponding U.S. Patent Pub. 2004/0133277, paragraph 0083, lines 9-11).

In rejecting independent claim 19, the Examiner indicates that Brantigan '915 teaches "in figure 9 a spinal implant having threads 33b," and "Johnson teaches in figure 1-32 an implant 10, comprising threads that are configured to prevent rotation (locking threads)." (Present Office Action, Page 2). According to the Examiner, "it would have been obvious to one having ordinary skill in the art at the time that the invention was made that the threads as taught by Johnson could be substituted for the threads as taught by Brantigan in order to prevent the implant from coming unfasten (sic) from the vertebrae." (Present Office Action, Page 2). However, contrary to the Examiner's contention, Applicant submits that no motivation exists to modify the implant Brantigan '915 with the teachings of Johnson, and, even if the Implant of Brantigan '915 was modified with the teachings of Johnson, the apparatus resulting from the modification would not include all the claim limitations of independent claims 1 and 19.

Johnson teaches a screw (10) adapted to be threadably received within a mating member (19). To that end, the screw (10) includes a locking thread (14), and the mating member (19) includes a standard internal thread (21). However, the locking thread (14) of Johnson is not similar to the above-discussed locking threads 53 of the present invention. Instead, the locking thread (14) is continuous with a variable lead or pitch. The variable lead or pitch of the locking thread (14) insures metal-to-metal contact with the standard internal thread (21), and, because the locking thread (14) and the standard internal thread (21) are metal and resist deformation, facilitates an interference fit therebetween. The interference fit afforded by the locking thread (14) serves in resisting vibration in order to maintain the screw (10) within the mating member (19). Accordingly, to maintain a fastener within a mating member, Johnson

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teaches that the fastener should include continuous thread with a variable lead or pitch for insuring metal-to-metal contact with a standard thread provided on the mating member, and, thereby, facilitating an interference fit between the fastener and the mating member.

Johnson does not teach an implant adapted for contact with portions of bone, but instead a fastener requiring metal-to-metal contact to function. Applicant submits that the continuous thread with a variable lead or pitch of the fastener of Johnson would not be suitable for contact with boney materials. Boney materials are significantly softer than metal. Therefore, if inserted into a tapped hole in a boney material, the fastener of Johnson would destroy the boney threads of the tapped hole. Rather than resisting deformation (like the standard internal thread (21) made of metal), the threads of the fastener of Johnson would crush the boney threads of the tapped hole. For similar reasons, self-tapping a hole in a boney material using the fastener of Johnson would also ultimately crush the boney threads formed thereby. In either approach then, the fastener of Johnson would preclude a secure connection with the boney material. Therefore, if the implant of Brantigan '915 was modified to include a continuous thread with a variable lead or pitch according to the teachings of Johnson, the resulting apparatus would also be precluded from forming a secure connection with the boney material that would resist backward rotation of the implant.

Because the fastener of Johnson would not be suitable for contact with boney materials, Applicant submits that no motivation would exist to modify the implant of Brantigan with the teachings of Johnson. Furthermore, because the apparatus resulting from modifying the implant of Brantigan with the teachings of Johnson would be precluded from forming a secure connection with a boney material, Applicant submits that the apparatus resulting from the modification would not include all the claim limitations of claims 1 and 19. Such an apparatus would not include "a helical thread formed on at least a portion of said outer surface...including at least one deviation adapted to resist backward rotation of said elongated body once it is inserted between the boney structures" as recited in claim 1, or include "at least one surface

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projection...being configured to resist backward rotation of said body once said body has been inserted between the portions of bone" as recited in claim 19. Therefore, Applicant submits that the Examiner has failed to provide a prima facie case of obviousness in rejecting independent claim 19, and submits that an identical rejection of independent claim 1 would fail for the same reason.

Applicant submits that independent claims 1 and 19 are patentable, and that dependent claims 10-18 and 20-31 dependent from independent claims 1 or 19, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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Dated: June 12, 2007

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